

Essential Elements for Documented Approval to Conduct Study at an Off-Campus Site

On **agency letterhead**, the letter from the Off-Campus site administrator should include the following:

- Investigator's first and last name.
- A statement that the site will receive a copy of the IRB approval letter.
- Specification of how the investigator will contact and/or recruit participants at the site and if permission is granted to collect data at the location.
- Summary of the protocol to confirm their understanding of the study. The agreed upon data collection methodologies must be specified.
- What the site had agreed to allow the investigator to do, including any restrictions or limitations and what responsibilities, if any, the site is assuming.
- Whether they will receive any benefits, including a copy of the study results.
- Time frame involved or any time restrictions.
- Off-Site Official's first and last name.
- Off-Site Official's signature.
- Off-Site Official's title.
- Off-Site Official's contact information.

The Off-Site Approval letter, as well as other supporting documentation, should be uploaded during initial IRB submission in LU Cayuse.

This template was developed by the Lamar University IRB to assist the investigators in the design of their Off-Site Approval letter. Information listed in the checklist needs to be included in the Off-Site Approval letters.

TEMPLATE ON FOLLOWING PAGE

Off-Site Letterhead

Lamar University IRB Approval #

Date

Dear Lamar University, Institutional Review Board,

I have reviewed the proposed study, [Study Title], presented by [Researcher's name], at Lamar University. I understand that the purpose of the study is to [Study Description]. Targeted participants will include [description of study population].

I have granted permission for the following research activities to be conducted at [Site Name].

[Complete description of the research protocol. This should also include how the researcher will contact and/or recruit participants, time frame involved, and whether participants will receive any benefits.]

I confirm that I have authority to grant such permission on behalf of [Site Name]. I understand that this project will begin once the researcher has obtained Lamar University Institutional Review Board (IRB) approval. [Researcher's name] has agreed to provide to my office a copy of the Lamar University IRB approval letter before beginning any research activities.

I understand that all data collected will be kept confidential. In accordance with [Site Name] policy and best practices for ethical research, I understand that neither participants nor sites will be identified in any report of findings or in the published study. The researcher has agreed to provide my office a copy of the aggregate results from the study.

If the IRB has any concerns about the permission being granted by this letter, please contact me at the phone number or email listed below.

Sincerely,

[Site Official's Signature]

[Site Official's Printed Name]

[Site Official's Title]

[Site Official's Contact Information]